CASE/0496/03/25

COMPLAINANT v MODERNA

Allegations regarding a press release shared on LinkedIn

CASE SUMMARY

This case was in relation to a LinkedIn post published by Moderna US, that included a link to a Moderna press release announcing the anticipated MHRA approval of its RSV vaccine, mRESVIA (mRNA-1345). The allegations centred around Moderna's UK employees' social media interactions with the US version of the press release, and a safety claim within that press release.

The outcome under the 2024 Code was:

Breach of Clause 5.1	**Failing to maintain high standards**
Breach of Clause 12.7	**Failing to include a black triangle**
Breach of Clause 14.2	**Failing to give a clear reference to published studies**
Breach of Clause 26.1	**Promoting a prescription only medicine to the public**

No Breach of Clause 6.1	**Requirement that claims must not be misleading**
No Breach of Clause 6.2	**Requirement that claims must be capable of substantiation**
No Breach of Clause 6.4	**Requirement that claims must reflect the available evidence regarding possible adverse reactions**
No Breach of Clause 8.3	**Requirement to certify non-promotional material**
No Breach of Clause 14.3	**Requirement to provide data on file to a health professional or other relevant decision maker**
No Breach of Clause 18.2	**Requirement to provide substantiation for claims at the request of a health professional or other relevant decision maker**

This summary is not intended to be read in isolation.
For full details, please see the full case report below.

FULL CASE REPORT

A complaint about Moderna Biotech UK Ltd was received from a contactable complainant who described themselves as a member of the public.

COMPLAINT

The complaint wording is reproduced below with some typographical errors corrected:

> "Dear PMCPA,
>
> I am writing to complain about a press release distributed by Moderna regarding its latest mRNA product to be licenced in the UK. The press release is dated 28th February 2025. Moderna may wish to claim that the press release was intended only for its investors. However, this press release was also distributed using its social media accounts so its intended audience obviously extended far beyond just its investors or the finance community. Here are examples of how the press release was distributed using its LinkedIn and X accounts respectively: [screenshots provided].
>
> I do understand that, as the press release originated outside the UK and as the social media accounts are not specific for Moderna's UK subsidiary or specifically targeted at a UK audience, then this matter may not necessarily have fallen within your jurisdiction. However, the social media message and therefore also the press release itself was 'liked' on LinkedIn by a number of UK-based employees of Moderna (including [named senior medical employee]) and I understand that this does bring the matter within your jurisdiction. Here is a sample of the LinkedIn accounts of UK Moderna employees which were used to 'like' the LinkedIn message above [screenshots provided].
>
> I note that the guidance on the section of your Code which deals with interactions with the public, patients and journalists says:
>
> *'Pharmaceutical companies need to ensure that proactive distribution of material meets the requirements of the Code, particularly the prohibition on advertising prescription only medicines to the public. It is difficult to see how the proactive distribution of a press release about a medicine to an individual member of the public would meet all the requirements of Clause 26.'*
>
> Following the 'likes' by numerous Moderna UK employees it appears to me that this press release, and the message posted on LinkedIn containing a link to it, do indeed promote a Prescription Only Medicine to the public – which I believe is illegal in the UK.
>
> I know that pharmaceutical adverts and press releases in the UK needs to be correctly examined and/or approved prior to use but I have no means of knowing whether this material was properly reviewed and/or approved for use in the UK in this way. However, because this material fails to comply with your Code in so many ways (see below) it seems unlikely to me that it has been.
>
> It is my understanding that this newly licenced medicine will be under close scrutiny for adverse events and that this status is signified by an inverted black triangle which is supposed to be included on all promotional material and certain other materials. I have, however, been unable to find a black triangle or any text about close scrutiny for adverse events in any of this material. In fact, the press release itself has very little to say at all about either the safety or efficacy profiles of the vaccine, merely saying that the approval was based on *'positive'* results from a large clinical study and *that 'no serious safety concerns were identified in the clinical trial'.* I am afraid that this is simply

not good enough. There are no usable clinical trial details cited in support these claims, which I understand is contrary to the requirements of your Code which states *'When promotional material refers to published studies, clear references must be given.'* Without such references, how is a reader such as myself supposed to be able to check the veracity of such claims? If the data are unpublished and classified as 'data on file' then the material should have said so in order that I could request it from Moderna (although I doubt Moderna would have provided it to me as it appears that I am not a suitably qualified person). As it happens, the UK government also published a press release about the approval of this vaccine. This government press release states that *'the most common side effects of the vaccine, which may affect more than 1 in 10 people, include swelling/tenderness in the underarm, headache, muscle ache, joint aches, pain at the injection site, tiredness and chills.'* I realise that this is simply a list of the most common side effects and that none of them may represent *'serious safety concerns'.* However, their severity (as opposed to their simple binary status as either serious or non-serious) may have varied greatly from mild to very severe and merely stating that *'no serious safety concerns were identified'*, however accurate, does not seem to me a sufficiently balanced and informative way of summarising the available safety information in the Moderna press release. I also realise that your Code allows that *'The validity of indications approved in the marketing authorisation can be substantiated by provision of the summary of product characteristics.'* However, contrary to what I believe the PMCPA considers to be best practice, no UK SmPC was included in the press release nor was there any link provided by which I could access it. Indeed, it would appear that as the government will not publish the SmPC until 7 days after the approval so I will be unable to assess the veracity of Moderna's claims until 6th March anyway. Why is a pharmaceutical company allowed to make claims about its products which were, it seems, impossible to verify? If Moderna are going to rely upon an SmPC for validation of claims about its product then surely they must wait for that SmPC to be available before they make such claims.

In summary, as a result of its UK employees 'liking' its LinkedIn message about the newly issued UK licence for its RSV vaccine, Moderna has breached your Code of Practice by:

- Promoting a POM to the public
- Making misleading safety claims that are unbalanced and do not reflect the available evidence fully and clearly
- Providing material that is insufficiently complete to enable recipients to form their own opinion of the therapeutic value of the medicine
- Failing to provide sufficient information to allow a reader to independently verify whether claims made are capable of substantiation or have any clinical or scientific validity
- Failing to make clear the status of the product as requiring additional monitoring in relation to adverse reactions
- Failing to get material appropriately examined and/or approved for use/distribution in the UK

Thank you for dealing with this matter."

When writing to Moderna, the PMCPA asked it to consider the requirements of Clauses 5.1, 6.1, 6.2, 6.4, 8.3, 12.7, 14.2, 14.3, 18.2 and 26.1 of the 2024 Code.

MODERNA'S RESPONSE

The response from Moderna is reproduced below:

> "We have addressed the points raised and to provide clarifications regarding the events in question below.
>
> Moderna accepts that in this case Moderna employees/contractors interacted with social media posts contrary to Moderna's social media policy and in doing so brought the posts within the scope of the Code. Moderna strives to comply with the Code requirements and, as described in detail below, has a comprehensive social media policy and related training in place. Moderna is therefore disappointed to have received this complaint and takes this matter very seriously, as demonstrated by our prompt action to address the matters raised.
>
> **BACKGROUND**
>
> On 27 February 2025, Moderna was informed by the MHRA of the anticipated approval of mRESVIA (mRNA-1345) within 24 hours. Moderna's UK team worked on a UK press release, which was finalized following review by the Regulatory Team, [named senior employees] A draft was also shared with the MHRA advertising team, per MHRA guidance for new products, and the content reviewed by the MHRA.
>
> Moderna US published a global press release using the same content as reviewed by the MHRA (with the black triangle removed for the US) in the corporate news section of Moderna US's website and released it to global media. It was clear from the location and format of the press release, including the subline 'CAMBRIDGE, MA / ACCESS Newswire / February 28, 2025 / Moderna, Inc. (NASDAQ:MRNA)' that it was a press release intended for a global investor audience.
>
> Moderna US's posts on its global LinkedIn and X accounts contained brief informative statements 'We announced today…' as shown in the screen shots, which did not refer to the product name, and provided a link to the press release within the media section on the Moderna US corporate website for those that wished to read more.
>
> In anticipation of the global announcement, and given the importance of ensuring compliance with the ABPI Code, the [senior UK leader] issued a proactive, specific instruction to all UK staff on 28 February 2025 (11:00 AM), explicitly directing that no UK-based employees should engage in any way with social media content relating to this news. This direct warning went beyond standard policy enforcement, was a pre-emptive measure to further mitigate potential risk and is recorded in our timeline below.
>
> This instruction, which we view as an example of our proactive and rigorous approach to compliance, complemented existing policy and training. It stated:
>
> 'Important compliance reminder: A press release will be issued globally, but there will be no UK social media posts related to this news. As a reminder, please do not engage with or share any social media content about mRESVIA, as it would not be compliant with the ABPI Code of Practice.'

Of the six individuals identified as 'liking' a post, two left Moderna in 2024 and were not employed or otherwise engaged by Moderna at the time they 'liked' the post. They had not updated their social media accounts to remove reference to Moderna as they are required to do on leaving and Moderna has contacted both individuals to request this is updated immediately.

Below is a timeline of relevant actions, relating to both the approval process of the materials in question and after-event actions following the receipt by Moderna of complaint 0496/03/25.

TIMELINE:

Date	Time	Action	Comments
27/02	02:00 PM	**Update from UK regulatory team that authorisation of mRESVIA was anticipated in next 24 hours**	UK press release was finalised with regulatory team
27/02	05:30 PM	**Moderna's UK draft press release shared with MHRA advertising team**	As per MHRA guidance for new product approvals.
28/02	10:30 AM	**MHRA's press release goes live**	**MHRA press release**
28/02	11:00 AM	**[senior UK leader] sends 'All UK staff' an email about the authorisation and imminent press release.**	Email included: 'Important compliance reminder: *A press release will be issued globally, but there will be no UK social media posts related to this news. As a reminder, please do not engage with* or share any social media content about mRESVIA, as it would not be compliant with the ABPI Code of Practice. If you receive any external inquiries, please direct them to the UK '*Communications team.'*
28/02	01:08 PM	**Comments returned from MHRA**	Comments from the MHRA Incorporated into Moderna's draft UK press release by UK communication/regulatory/medical and uploaded to PromoMats for final approval and certification
28/02	02:00 PM	**An article regarding authorisation is published on Moderna intranet**	Article included: 'Important Compliance Reminder: UK-based colleagues are reminded not to engage with or share any social media

			content about mRESVIA, as it would not be compliant with the ABPI Code of Practice. If you receive any external inquiries, please direct them to the UK communications team
28/02	02:50 PM	**Review complete in PromoMats**	Press release approved and certified by [senior medical employee] in Veeva
28/02	03:00 PM	**Moderna's US press release published on global website and issued to global media (no black triangle)** **Moderna UK's press release issued to UK media (with black triangle)**	Moderna US finalized a global press release based on the Moderna UK press release and then published this on Moderna US's global corporate website and released it to global media. Version published on global website did not include reference to NEJM paper. This was added at 1430 on 05/03 when alerted of the PMCPA complaint in question. Moderna US's global press release was NOT published on Moderna's UK website and social media content from Moderna US's global corporate channel was NOT geotargeted to the UK. A referenced version was issued to UK media.
05/03	12:56 PM	**Moderna receives complaint Case/0496/03/25**	Moderna receives the PMCPA complaint relating to the allegations regarding the alleged interaction of Moderna UK employees with Moderna US's global press release shared on LinkedIn and X.
05/03	01:04 PM	**Internal efforts to identify people named in the claim**	Moderna checks every person identified by the complainant and their status in its internal systems, including whether or not they are still employed by Moderna and whether they 'liked' the post. We then launch a further review of all people who have liked the post to potentially identify additional Moderna people.
05/03	04:06 PM	**[Senior medical employee] sending correspondence to people named in the claim**	Each Moderna employee named in the complaint was contacted by Moderna's [senior medical employee].

05/03	04:50 PM	**[Senior UK leader] sends a reminder to 'All UK staff' about the ABPI rules**	Further communication sent out to 'All UK staff', being all those employed or otherwise engaged in the UK, to repeat that UK staff must not interact (like, share, comment) with ANY company social media content unless it carries the hashtag #ModernaUK which is used to indicate which material that has received approval for use within the UK.
11/03	04:57 PM	**[Senior medical employee] sending correspondence to another person identified who like the post**	A further review of engagement with the particular LinkedIn post identified another Moderna individual that liked the post – Moderna contacted that person and the like has been removed. This was an individual contractor in Moderna's engineering team.

We have repeatedly conveyed firm instructions to all UK employees regarding social media engagement (including LinkedIn) and specifically communicated that no social media engagement was allowed for this particular announcement, consistent with ABPI Code requirements.

Moderna maintains strict social media policies at both a global and local UK level to ensure compliance with industry standards, regulatory requirements, and corporate integrity. This framework establishes overarching principles that apply universally to all employees and affiliates, ensuring consistency in how the company is represented. Global rules are then adapted at a local level to align with specific legal and cultural requirements in each jurisdiction, providing a tailored approach to regulatory compliance while maintaining a unified corporate standard.

Under the framework, UK employees are subject to both the Global Social Media policy and UK Local Social Media Guidelines, which explicitly prohibit engagement with social media content in ways that could breach UK pharmaceutical regulations and the ABPI Code. Our framework limits UK employees from interacting with specific posts and publication, such as:

1. Controlled Engagement with Corporate Content – Employees may only interact with posts from Moderna's official corporate channels and only when the post includes the hashtag *#ModernaUK*. Any engagement outside of this scope—including likes, shares, or comments—is considered non-compliant.
- Ban on Interacting with Product-Related Content – Employees must not comment on, like, or share any posts that mention a drug product, pipeline candidate, or make claims about safety or efficacy. This includes posts from both Moderna and external sources.
- Disclosure Requirements for Engagement – Where engagement is permitted (e.g., posts containing *#ModernaUK*), employees must list Moderna as their employer in their social media bio to ensure transparency.

Moderna UK employees received training on the social media framework by Global Compliance Team. Staff are routinely trained on the appropriate use of social media,

including an induction session on joining. Every new employee joining Moderna UK is trained on the ABPI Code rules, including on Moderna's social media guidelines. Training is provided by [senior medical employee] once every quarter to employees who joined Moderna in this period.

Staff are routinely trained on the appropriate use of social media, including an induction session on joining. Moderna UK proactively reinforces compliance through regular communication to the UK organisation relating to social media activity. Over a period of several months prior to this particular complaint arising, multiple reminders had been sent to the Moderna UK organization, providing guidance on highlighting social media engagement risks, and inviting staff members to mandatory compliance sessions. These messages, sent consistently over several months, provide practical examples, highlight ABPI Code cases, and emphasize the importance of maintaining compliance in all professional interactions. This ongoing engagement ensures that employees remain aware of and should adhere to the highest ethical standards relating to social media activity.

In relation to the individuals in question, as described above, two individuals were not employed by Moderna at the time they 'liked' the post. Both had completed compliance training including on social media while at Moderna. Of the other four individuals, three joined in 2024 and of those two had attended induction compliance training. One was unable to attend their scheduled session and will attend the next session.

Upon receiving PMCPA's letter dated 5 March 2025, our [senior medical employee] promptly notified the colleagues referred to in the complaint and requested that they remove any such engagement and re-iterating the communication previously circulated by the [senior UK leader]. As noted above, 2 of individuals identified by the complainant are no longer employed or otherwise contracted by Moderna nor had they been at the time of the of the LinkedIn post being published. We promptly reached out to all those employees or contractors identified to request that they rectify the position and continue to try and engage with those no longer contracted by Moderna to do the same.

The communication circulated to those identified in the complainant's complaint specifically stated:

'If you have engaged with the post in any way—by liking, commenting, or sharing—we kindly ask that you unlike the post and remove any comments or shares as soon as possible.'

Our [Senior Medical employee] did not intentionally 'Like' the post. It appears our [Senior Medical employee] inadvertently pressed the 'Like' button while conducting proactive compliance monitoring activities on social media engagement activity on to ensure no UK employees or contractors were actively engaging. The LinkedIn mobile interface places engagement tracking and the 'Like' button in close proximity, leading to our [Senior Medical employee] inadvertently liking the post, as had been identified by the complainant. This was immediately rectified. This is further re-enforced by the actions of the [Senior Medical employee] during the approval process of materials associated with this complaint. In particular, [they] stated:

'As a reminder, all external communications, including social media engagement, must align with approved company materials and the ABPI Code of Practice. Your cooperation in swiftly addressing this matter is essential to maintaining compliance and protecting both the company and yourselves.'

Moderna immediately launched a thorough review of the list of individuals to make sure any individuals who have engaged with the posts are aware of the clear instructions previously provided. We are still monitoring it to be able to promptly address any potential concerns.

The above reflects our commitment to swift remedial action to ensure compliance with the ABPI Code.

We are doing, and have done, our utmost to prevent and/or rectify any inadvertent noncompliance swiftly. We took these actions to uphold the standards expected under the ABPI Code of Practice.

Compliance With the ABPI Code

Considering the specific Clauses referenced—5.1, 6.1, 6.2, 6.4, 8.3, 12.7, 14.2, 14.3, 18.2, 26.1—Moderna's actions to comply stated below:

ABPI Clause		**Moderna Action**
5.1	**Companies must maintain high standards at all times.**	Moderna strives to maintain high standards regarding its social media presence and communication to the public. As described in more detail above, Moderna has a strict social media framework in place and have trained its employees on how to avoid any potential violation. Regarding the LinkedIn and X post referenced in this complaint, Moderna sent out a specific communication to all its UK employees in advance asking them not to engage with any social media posts related to this matter. Moderna further continued its efforts after receiving the compliant, taking swift steps to remind employees of the importance not to interact on social media with such content and requesting the immediate removal of any such interactions to ensure compliance with the ABPI Code of Conduct (following also clauses 18.2 and 6.1). Moderna has social media policies that clearly communicate corporate standards, expectations and behaviours with appropriate training in place in accordance with the supplementary

		information to clause 5.1 of the Code, and therefore believes it has taken reasonable steps to maintain high standards at all times in line with clause 5.1.
6.1	**Information claims and comparisons must be accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence and reflect that evidence clearly. They must not mislead either directly or by implication, by distortion, exaggeration or undue emphasis. Material must be sufficiently complete to enable recipients to form their own opinion of the therapeutic value of the medicine.**	Information in UK press release was substantiated, accurate, balanced, fair, objective and unambiguous and it was based and reflected evidence. UK press release was reviewed and certified by the [senior medical employee] before distribution, in line with Clauses 8.3, 14.2, 14.3. The information included in the UK press release was accurate, balanced, fair, objective and unambiguous, it was unbiased and reflected evidence. The wording 'no serious safety concerns were identified' referred to by the complainant is an accurate and fair representation of the evidence, is capable of substantiation based on the trial data, and does not state or suggest that the product has no adverse reactions. This wording was reviewed by the MHRA. All the referenced studies mentioned in the UK press release have been fully referenced and substantiated. The claims were not impossible to verify as suggested by the complainant – the complainant could have contacted Moderna and requested substantiating information. Moderna therefore believes that the content complies with clauses 6.1, 6.2 and 6.4 of the Code.
6.2	**Any information, claim or comparison must be capable of substantiation. Companies must provide substantiation, following a request for it as set out in Clauses 14.3 and 18.2. In addition, when data from a clinical trial is used, companies must ensure that where necessary, that trial has been registered and the results disclosed in accordance with Clause 4.6.**	
6.4	**Information and claims about adverse reactions must reflect available evidence or be capable of substantiation by clinical experience. It must not be stated that a product has no adverse reactions, toxic hazards or risks of addiction or**	

	dependency. The word 'safe' must not be used without qualification	
8.3	**Material issued by companies which is not required to be certified under the Code should be examined by a signatory or an AQP, who needs not be a signatory, to ensure that it does not contravene the Code or the relevant statutory requirements. Such material might include corporate advertising, press releases, market research material, financial information to inform shareholders, the Stock Exchange and the like, and written responses from medical information departments or similar to unsolicited enquiries from the public, etc.**	The UK press release was approved by Moderna UK's ABPI Signatory. The UK press release was reviewed by the MHRA, all the suggested changes were implemented and then it was approved by [senior medical employee] (Moderna UK ABPI signatory) in Moderna internal system Veeva in compliance with clause 8.3 of the Code. The Global press release was not approved by the Moderna UK ABPI Signatory as it was for publication by Moderna US on its global corporate website and was not being published nor geotargeted for the UK public.
12.7	**Digital materials are also covered by this requirement, and the black triangle symbol should be located adjacent to the first mention of the product as this is likely to be considered the most prominent display of the name of the product. The size and location must be such that it is easily located.**	The UK press release included the black triangle symbol. The certified UK press release included the black triangle symbol and appropriate references in accordance with clause 12.7. The Global press release did not include the black triangle, and there was not a requirement for it to be included as this material was not intended for a UK audience.

14.2	**When promotional material refers to published studies, clear references must be given.**	The UK press release was not intended to be promotional material, and it was intended only for investors and not members of the public. All studies mentioned in the UK press release have been fully referenced and substantiated. The Global press release was not been intended for a UK audience nor to be promotional.
14.3	**When promotional material refers to data on file, the relevant part of that data must be provided as soon as possible, and certainly within ten working days, in response to a request from a health professional or other relevant decision maker.**	The press release is not promotional material, does not refer to 'data on file' and Moderna did not receive any request from a health professional or other relevant decision maker to provide such data.
18.2	**Substantiation for any information, claim or comparison must be provided as soon as possible, and certainly within ten working days, at the request of health professionals or other relevant decision makers.**	Moderna did not receive any request for substantiation for any information, claim or comparison from a health professional or other relevant decision maker.
26.1	**Prescription only medicines must not be advertised to the public.**	There was no intention by Moderna to promote a prescription medicine. to the UK public. The UK press release was intended only for investors and was approved accordingly with Clause 8.3. The global press release was not intended for the UK general public, as evidenced by Moderna reminding all employees in the UK not to engage with it by the communication circulated to 'All UK Staff' in advance of any external communication by our [senior UK leader] to emphasise the importance of refraining from interacting with any social media posts in this regard. Moderna has also a strict Social Media Policy in place and has trained its employees on it. However, Moderna accepts that by employees liking the global social media posts, this action

		could be considered under the Code as promoting a prescription medicine to the public, notwithstanding that Moderna took reasonable steps to prevent such actions and the product name is not mentioned in the social media posts.

Following our thorough internal review, we are confident that there was not an intentional breach of the ABPI Code. Moderna had already taken significant steps to prevent such cases from arising and will continue to do so having rigorously communicated with our employees, reminding them of the Code requirements, and our internal social media policy and mitigating potential future risk where possible.

Moderna remains fully committed to complying with the ABPI Code of Practice and ensuring that all staff, materials, and communications uphold the highest ethical and professional standards. We have put robust mechanisms in place to prevent improper social media engagement, and we reacted promptly upon learning that the post in question might inadvertently have been 'liked.'

We trust that this explanation clarifies the circumstances and demonstrates our proactive steps to address any potential issues. Should the PMCPA require further documentation please do not hesitate to let me know. We will be happy to provide any supplementary materials you deem necessary."

PANEL RULING

This complaint was in relation to a LinkedIn post published by Moderna US with a link to a Moderna press release that announced the anticipated MHRA approval of its RSV vaccine, mRESVIA (mRNA-1345). The allegations centred around Moderna's UK employees' social media interactions with the US version of the press release, and a safety claim within that press release.

The press release

In its response to the complaint, Moderna provided the UK version and the US version of the press release. The title of both was *"Moderna received Medicines and Healthcare products Regulatory Agency Marketing Authorisation in the UK for RSV Vaccine*". Both versions of the press release contained broadly similar text, but had some important differences, which are considered as part of this ruling.

Moderna confirmed that the UK version of the press release had been certified by an ABPI signatory and the requirements of the ABPI Code had been considered in relation to it. However, the complainant alleged that, when the US version of the press release was posted by Moderna's US corporate LinkedIn account, that post was 'liked' by UK employees of Moderna, which brought it within scope of the ABPI Code.

Moderna's response to the complaint acknowledged that the UK employees that had 'liked' the post included a senior medical employee, four other current employees and two ex-employees. Moderna also accepted that, although the US press release had been based on the UK press

release, the US version had not been approved by Moderna UK, and was not intended for the UK public.

The complaint

The Panel interpreted the complaint as relating to the following allegations:

1. The 'likes' of the LinkedIn post containing the US press release promoted a prescription only medicine (POM) to the public (Clause 26.1)

2. The US press release was not appropriately approved for use in the UK (Clause 8.3)

3. The US press release did not include a black triangle (Clause 12.7) nor a citation for a referenced clinical study (Clause 14.2)

4. Alleged breaches of Clauses 14.3 and 18.2

5. The US press release's claim that "*no serious safety concerns were identified*" was "*misleading, unbalanced and did not reflect the available evidence fully and clearly*" (Clauses 6.1, 6.2 and 6.4)

6. Failure to maintain high standards (Clause 5.1)

The Panel ruled on each of these allegations in turn, but firstly dealt with the question of the applicability of the ABPI Code in relation to a US press release.

Scope of the Code

The Panel concluded that the US press release had been brought within scope of the UK Code in two different ways. The first is due to Clause 1.2 of the Code, the relevant text of which says:

"*Information or promotional material about medicines which is placed on the internet outside the UK will be regarded as coming within the scope of the Code, if it was placed there by:*

- *…*
- *an affiliate of a UK company … and it makes specific reference to the availability or use of the medicine in the UK.*"

The US press release was placed on the internet outside the UK via a Moderna affiliate; its US-based parent company. The whole purpose of the US press release was to announce approval of the vaccine by the MHRA - the UK medicines regulator. The Panel considered that it was

clear that the press release made specific reference to "*the availability or use of the medicine in the UK*" for the purposes of Clause 1.2 and was therefore within scope of the ABPI Code.

The second reason this matter was in scope of the ABPI Code is dealt with under the Panel's ruling on Clause 26.1

The 'likes' of the LinkedIn post containing a link to the US press release promoted a POM to the public (Clause 26.1)

Although the complainant provided X (formerly Twitter) and LinkedIn posts by Moderna's US parent company as part of their complaint, the allegations appeared to relate solely to the 'likes' of the LinkedIn posts by Moderna's UK employees. The Panel therefore ruled on the basis of the LinkedIn post and associated press release only.

Moderna accepted in its response that the LinkedIn post by its US parent company, which linked to the US press release, had been 'liked' by several UK employees (including a senior medical employee). By doing so, the Panel considered that the LinkedIn post and US press release would have been disseminated proactively to a UK audience.

The Panel considered that it was irrelevant that the press release may have been intended for a US audience and/or only for the media and investors - once these multiple LinkedIn 'likes' had occurred, the US press release had been disseminated to the public in the UK. The LinkedIn followers of the Moderna UK employees, who had interacted with the post, would have been very likely to include UK health professionals and/or members of the UK public. It therefore followed that the US press release (that referred to a POM - mRESVIA (mRNA-1345)) had been promoted to the public by Moderna UK employees.

Notwithstanding the relatively factual nature of the press release, the Panel considered that the reference to the drug name and indication, the absence of any mention of the intended audience, and the way it had been disseminated on social media had made it promotional.

The Panel ruled a **breach of Clause 26.1** on that basis.

The US press release was not certified for use in the UK (Clause 8.3)

Clause 8.3 provides that certain types of non-promotional material must be certified in a similar manner to the certification of promotional material under Clause 8.1. The Panel noted the reference to press releases in the supplementary information to Clause 8.3 (under the heading "Examination of Other Materials") as an example of non-promotional material that requires examination rather than certification.

The Panel relied upon its ruling above in which it had concluded that the US press release was promotional due to its dissemination to the UK public via LinkedIn . On this narrow technical basis (that the press release was promotional), the Panel ruled **no breach of Clause 8.3**.

The US press release did not include a black triangle (Clause 12.7) or a citation for a referenced clinical study (Clause 14.2)

The UK version of the press release included a black triangle (as required by Clause 12.7) and a reference to a New England Journal of Medicine article about the vaccine, that was used to

substantiate the clinical trial information in the press release. However, the black triangle and the journal reference had been removed from the US version of the press release, on the basis that Moderna had not intended the US press release to be for a UK audience.

Given the Panel's rulings above that the LinkedIn post 'likes' by Moderna's UK employees had resulted in the US press release becoming promotional material in the UK, it follows that a black triangle and a clear reference to a published study referred to in that promotional material, should have been included. Due to the absence of both these requirements from the US press release, the Panel ruled a **breach of Clause 12.7 and Clause 14.2**.

Alleged breaches of Clauses 14.3 and 18.2

Part of the complaint alleged that if data was unpublished and classified as 'data on file', it "*should have said so in order that I could request it from Moderna*". The Panel interpreted this as being a reference to Clause 14.3. In addition, the complainant also referred to the Code requirement "*the validity of indications approved in the marketing authorisation can be substantiated by provision of the summary of product characteristics," which is* a requirement of Clause 18.2.

However, the Panel considered that the press release did not include data on file and Clause 14.3 was therefore inapplicable. In addition, Clause 14.3 (and Clause 18.2) both include two prerequisites. The first is that a request must be made to the company. The second is that these clauses only refer to providing data on file / substantiation if the request is made by a health professional or other relevant decision maker.

The complainant had not provided any evidence that they had made such a request to Moderna under either of these clauses, nor that they met the definition of a health professional or other relevant decision maker.

The complainant has the burden of proving their complaint and the Panel concluded that they had failed to do so in relation to these allegations. The Panel therefore ruled **no breach of Clause 14.3 and Clause 18.2**.

The US press release's claim that "no serious safety concerns were identified" was "misleading, unbalanced and did not reflect the available evidence fully and clearly" (Clauses 6.1, 6.2 and 6.4)

Based on the wording of the complaint, the Panel interpreted all of the complainant's allegations under Clause 6 to relate to the vaccine claim in the press release; that: "*no serious safety concerns were identified*". The allegations were that this amounted to a breach of Clauses 6.1, 6.2 and 6.4.

The Panel firstly considered the overall intention of the press release. In the Panel's view, the purpose and focus of the press release was to announce MHRA approval of the vaccine; not to provide a prescribing guide, nor to provide detailed information about efficacy and safety. The Panel acknowledged that, in the context of a one-page press release that was relatively factual

about the MHRA approval, it was not unbalanced to include one sentence about efficacy and then one sentence about safety in relation to the Phase 3 clinical trial.

The press release did not claim that the vaccine had no side effects, nor did it claim that it was "*safe*". The Panel considered the statement that there were "*no serious safety concerns*" is not the same as stating that there were *no* safety concerns, or that the vaccine had no adverse reactions.

The Panel concluded that the complainant had not established why this safety claim was not an accurate reflection of the current data and available evidence, nor why the material was insufficiently complete. The absence of a reference, or the SPC, did not mean that the claim could not be substantiated. The Panel concluded that the complainant had failed to discharge their burden of proof in relation to this aspect of their complaint.

Based on the above factors, the Panel ruled **no breach of Clauses 6.1, 6.2 and 6.4**.

Failure to maintain high standards (Clause 5.1)

The Panel noted Moderna's submission that the senior medical employee that had 'liked' the LinkedIn post had done so accidentally, and that the other employees that had done so were relatively new in post, or had recently left. Two employees that had engaged with the post had left employment with Moderna in 2024 and had not updated their profiles to remove the reference to Moderna. The Panel also acknowledged that Moderna did have global and local social media policies in place, and it had provided evidence of communications being sent to staff (including about this specific press release) to remind them about Code compliance on social media.

Nevertheless, the Panel considered that this was clearly not an isolated incident relating to only one individual error. The LinkedIn post had been 'liked' by several current Moderna UK employees, including a senior medical employee. The Panel considered that the senior medical employee would have likely had a reasonably large LinkedIn following, as well as influence over junior colleagues who may have been tempted to replicate their interaction with the post.

The Panel also took account of Moderna's failure to recognise that Clause 1.2 of the Code applied to the US press release. Moderna US (an affiliate for the purposes of Clause 1.2) had placed material on the internet outside the UK, but it referenced the availability of the medicine in the UK. Indeed, the whole purpose of the press release was to announce MHRA approval and even the heading of the press release referred to the UK. Given the US press release was largely based on the UK press release, the Panel would have expected Moderna to have recognised the applicability of the UK Code in these circumstances.

For these reasons, the Panel concluded that Moderna had failed to maintain high standards and ruled a **breach of Clause 5.1**.

Complaint received **2 March 2025**

Case completed **13 June 2025**